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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/052,386	01/18/2002	Anil K. Saksena	IN01159K1	5995

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SCHERING-PLOUGH CORPORATION  
PATENT DEPARTMENT (K-6-1, 1990)  
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EXAMINER

MONDESI, ROBERT B

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 02/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/052,386	<b>Applicant(s)</b> SAKSENA ET AL.	
	<b>Examiner</b> Robert B Mondesi	<b>Art Unit</b> 1653	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 January 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-66 is/are pending in the application.  
4a) Of the above claim(s) 35-38, 44-49 and 66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-34, 39-43 and 50-65 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Status of the numbering of the claims***

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered **claims 30-63** have been renumbered **claims 29-62**.

Since there are two claims numbered 63, the first claim marked 63 will become claim 62. The numbering of the claims from 63-66 will remain the same.

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-34, 39-43 and 50-65 drawn to peptides and pharmaceutical compositions, classified in Class 514, subclass 17.
- II. Claims 35-38, 44-49 and 66, drawn to process of use or method of treatment of Hepatitis C, classified in Class 424, subclass 9.1.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of

using that product (MPEP § 806.05(h)). In the instant case: product can be used in the alternative processes of apoptosis of cells.

This application contains claims directed to the following patentably distinct compounds of the claimed invention: In claims, 1-34 the presence of a compound general structure formula (Formula 1) and the ability to substitute a variety of independently selected moieties in positions A, E, G, J, L, M, Q, W, Y, Z, R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub> and R<sub>4</sub> has given rise to a multitude of compounds. Each one of these compounds is patentably distinct absent factual evidence to the contrary.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed moiety in positions A, E, G, J, L, M, Q, W, Y, Z, R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub> and R<sub>4</sub> that is searchable for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, the moieties selected in positions A, E, G, J, L, M, Q, W, Y, Z, R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub> and R<sub>4</sub> in the general formula (Formula I) are set forth in a series of alternatives.

Applicant is advised that a reply to this requirement must include a single moiety in positions A, E, G, J, L, M, Q, W, Y, Z, R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub>, and R<sub>4</sub> that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should applicant traverse on the ground that the peptides are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the peptides to be obvious variants or clearly admit on the record that this is the case. In

either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention. This application contains claims directed to the following patentably distinct compounds of the claimed invention: In claims 39-43 a multitude of compounds are presented. Each one of these compounds exhibits different biological properties, for example some of the compounds can be proton donors involved in acid base reactions and some of the other compounds can participate more readily in a SN1 type reaction. Each one of these compounds is patentably distinct absent factual evidence to the contrary.

Applicant is required under 35 U.S.C. 121 to elect a single compound from the group of compounds presented in claims 1-34, 39-43, and 50-65.

Applicant is advised that a reply to this requirement must include a single compound from the list of compounds that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should applicant traverse on the ground that the peptides are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the peptides to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and since they have acquired a separate status in the art as shown by their different classification and/or divergent subject matter, and/or are separately and independently searched, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims

and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

During a telephone conversation with Mr. Harvey Cohen on January 14, 2004 a provisional election was made with traverse to prosecute the invention of Group I, **claims 1-34, 39-43 and 50-65**. Affirmation of this election must be made by applicant in replying to this Office action. **Claims 35-38, 44-49 and 66** withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

***Priority***

The current application filed on January 1, 2002 is a CIP of 09/908,955 filed on July 19, 2001, which in turn claims priority to provisional application, 60/220,108 filed on July 21, 2000.

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

***Information Disclosure Statement***

The Information Data Sheets (IDS)s filed August 6, 2002 and November 14, 2003 have been received and are signed and considered, a copy of the Information Data Sheets (IDS)s is attached to the following document.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 30, 33, 39-40, 42, 51-60 and 63** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.



**Claim 30** provides for the use of a pharmaceutical composition, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

In **claim 33 and 63** the phrase "still additionally" is indefinite.

In **claims 30, 39-40 and 51-60** "HCV" needs to be spelled out in the first instance of use.

In **claim 42 and 63** "PEG" needs to be spelled out in the first instance of use.

In claims 63 and 66, a large blank space exists between the written segment of the claim and the segments of the claim that provides the chemical structures of the compounds of the invention. Removal of these blank segments will overcome the rejection.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

**Claim 30** is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

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Insofar as this is a composition claim, the process recited does not per se modify the composition and therefore has no applicable patentable weight.

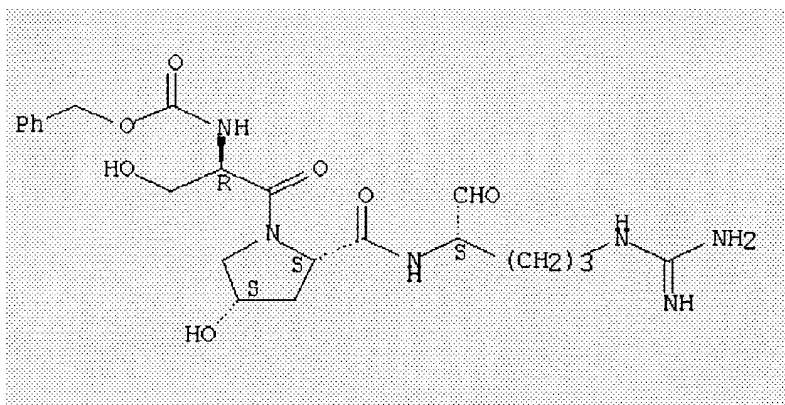
### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1 and 2** are rejected under 35 U.S.C. 102(b) as being anticipated by Brunck et al. WO 00/05245. Brunck et al. teach, (pages 33, line 12, to page 43 line 7, and claim 1, pages 159-167), the following structure;



**Claim 1** recites a structure according to the compound Formula I, with the following limitations; J may be (CH<sub>2</sub>), G may be (CH<sub>2</sub>), L may be CH, E may be CH, Q and M may be absent and when Q and M are absent A is directly linked to L, A may be O, R<sub>1</sub> may be COR<sub>5</sub> and R<sub>5</sub> may be OH, R<sub>2</sub> may be an amino, R<sub>3</sub> may be an C<sub>1</sub>-C<sub>10</sub> alkyl where said alkyl is optionally substituted with a hydroxy, Z may be N, R<sub>4</sub> may be H, W may be C=O and Y may be an alkoxy. **Claim 2** is a further limitation of **claim 1** that

states R<sub>1</sub> may be COR<sub>5</sub> and R<sub>5</sub> may be OH. Thus Brunck et al. teach all the elements of **claims 1 and 2** and these claims are anticipated under 35 USC 102(b).

### ***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

**Claims 1-34, 39-43, 50-65**, are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of **claims 1-34, 39-43, 50-65** of copending Application No. 09/908955. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. Compounds in **claim 39**, from page 631 to page 665 of present application, are identical to compounds in claim 39 of

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pending application No. 09/908955. Therefore **claim 39** of present application falls within the scope of **claim 39** of copending application No. 09/908955.

### **Conclusion**

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0198.

*RBM*  
Robert B Mondesi  
Patent Examiner  
Group 1653  
1-26-04

*Christopher S. F. Low*  
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